

**REMARKS**

Claims 86-103 were pending in the present application. Claim 86 has been amended and claims 93, 94, 102 and 103 have been canceled. The remarks made herein are designed to place the case in condition for allowance. As such, Applicants respectfully request that the remarks made herein be entered and fully considered.

**Drawings**

The Examiner objected to the drawing because sequences presented within the sequence listing were duplicated within certain figures. The Examiner requested that Applicants delete such figures and amend the specification accordingly. Applicants have deleted the figures which were duplicative with the sequence listing and have amended the specification as requested by the Examiner. Applicants submit herewith replacement drawings. For the Examiner's convenience, Applicants additionally submit herewith Appendix A which is a table listing the previous figure numbers and the new figure numbers.

**Specification**

The Examiner objected to the specification because 1) the title was not descriptive and 2) the status of all priority applications was not up to date. Applicants have amended the title to read "Anti-Tango294 Antibodies and Uses Thereof" and Applicants have amended the Related Applications section to update all of the priority information, thereby rendering the Examiner's objections moot.

**The Rejection of Claims 86-92 and 95-101 under 35 U.S.C. §112,****First Paragraph, Should Be Withdrawn**

Claims 86-92 and 95-101 were rejected under 35 U.S.C. §112, first paragraph, "[a]s containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Specifically, the Examiner states that "[t]he specification fails to provide the deposit statement, which would satisfy the enablement requirement under 35 U.S.C. 112." Applicants submit herewith a signed deposit statement, as requested by the Examiner. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. §112, first paragraph rejection.

**Rejection of claims 86-92 under 35 U.S.C. §112, first paragraph**

Claims 86-92 were also rejected under 35 U.S.C §112, first paragraph, as “[c]ontaining subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Specifically, the Examiner states that “[t]he claims encompass antibodies that bind to epitopes not found in the particularly disclosed sequence.”

Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner’s rejection, Applicants have amended claim 86 to increase the recitation of 90% to 95%.

“The written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed’” *See Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). In particular, an adequate description can be made by disclosing identifying characteristics, such as complete or partial structure, functional characteristics, or physical and/or chemical properties. “Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph ‘Written Description’ Requirement,” 66 Fed. Reg. 1099 (January 5, 2001). An Applicant may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id.* As mentioned above, newly pending claim 86 recites antibodies that specifically bind to a polypeptide selected from the group consisting of:

- a) a polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:415 or SEQ ID NO:416;
  - b) a polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of the DNA insert of clone EpT294, which was deposited with ATCC as Accession Number 207220;
  - c) a polypeptide which is at least 95% identical to the amino acid sequence of SEQ ID NO:417;
  - d) a polypeptide which is at least 95% identical to residues 15-423 of the amino acid sequence of SEQ ID NO:417; and
  - e) a polypeptide which is at least 95% identical to residues 34-254 of the amino acid sequence of SEQ ID NO:417;
- wherein the polypeptide exhibits a lipase activity.

The recitation of at least 95% sequence identity is a *very predictable structure* of the sequences encompassed by the claimed invention. The Examiner is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2001). Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention, *i.e.*, antibodies which specifically bind to the polypeptide variants recited in claim 86.

Furthermore, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. *See Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), *citing Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of DNAs may therefore be described by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus, or by means of a recitation of structural features common to the genus, which features constitutes a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); see also Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, first paragraph, “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (2001). The recitation of a predictable structure of at least 95% sequence identity to SEQ ID NO:415, 416 or 417 is sufficient to satisfy the written description requirement.

As indicated above, an applicant may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. The claimed antibodies specifically bind to polypeptides having lipase activity, thus the claims provide a functional characterization of the antibodies claimed in the genus.

Example 14 of the Revised Interim Written Description Guidelines is directed to a generic claim: a protein having at least 95% sequence identity to the sequence of SEQ ID NO:3, wherein the sequence catalyzes the reaction A to B. The Training Materials concludes that the generic claim of Example 14 is sufficiently described under 35 U.S.C. §112, first paragraph, because 1) “the single sequence disclosed in SEQ ID NO:3 is representative of the genus” and 2) the claim recites a limitation requiring the compound to catalyze the reaction from A to B. The Guidelines conclude that one of skill in the art would recognize the necessary attributes possessed by the members of the genus.

Following the analysis of Example 14, Applicants submit that newly pending claim 86, and dependent claims 87-92, satisfy the written description requirements of 35 U.S.C. §112, first paragraph. Specifically, the claims of the present invention encompass antibodies which specifically bind to a polypeptide selected from the group consisting of:

- a) a polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:415 or SEQ ID NO:416;
  - b) a polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of the DNA insert of clone EpT294, which was deposited with ATCC as Accession Number 207220;
  - c) a polypeptide which is at least 95% identical to the amino acid sequence of SEQ ID NO:417;
  - d) a polypeptide which is at least 95% identical to residues 15-423 of the amino acid sequence of SEQ ID NO:417; and
  - e) a polypeptide which is at least 95% identical to residues 34-254 of the amino acid sequence of SEQ ID NO:417;
- wherein the polypeptide exhibits a lipase activity.

As in Example 14, the specification discloses the amino acid sequence of SEQ ID NO:417 and the nucleic acid sequences encoding the Tango 294 polypeptide, and the claims recite a limitation requiring the polypeptide to have a specific function (*i.e.*, lipase activity).

In summary, the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Applicants submit that the relevant identifying physical and chemical properties of the disclosed genus would be clearly recognized by one of skill in the art and consequently, the Applicant has disclosed the necessary common attributes or features of the elements possessed by the members of the genus. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 86-92.

CONCLUSIONS

In view of the amendments and remarks made herein, Applicants respectfully submit that the objections and rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is believed that this paper is being filed timely as a request for a two month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.


Entry of the remarks made herein is respectfully requested.

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Respectfully submitted,

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